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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/687,449

10/16/2003

Ellen M. Heath

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EXAMINER

GORDON, BRIAN R

ART UNIT

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1743

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/687,449	<b>Applicant(s)</b> HEATH ET AL.	
	<b>Examiner</b> Brian R. Gordon	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10-16-03.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 41-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-40, drawn to a computer system and computer readable medium, classified in class 702, subclass 19.
  - II. Claims 41-46, drawn to a method for defining a protocol for DNA isolation, classified in class 364, subclass 130.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the product is not used in the process.

2. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.
4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Daniel Polglaze on June 19, 2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-40. Affirmation of this election must be made by applicant in replying to this Office action. Claims 41-46 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Information Disclosure Statement***

7. The information disclosure statement filed January 16, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

#### ***Specification***

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

requested in correcting any errors of which applicant may become aware in the specification.

9. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: As to claim 3, . No portion of the specification discusses the step of removing liquid by aspiration with respect to gentle or vigorous rates. Furthermore there is no support for the wherein clause of claim 34 directed to external control of each sub-module.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 3-6, 11, 15-21, 24, and 35-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "the biological sample" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the remaining material" in the next to last line on page 25. There is insufficient antecedent basis for this limitation in the claim.

In claim 3 there are two steps of mixing the sample. It is unclear what sample is being mixed each step. Is it "the sample" or "the biological sample". Where are the samples located?

It is unclear which vessel is referenced by the term "the vessel" in claim 4.

Claim 5 is directed to further dispensing additional reagents, however claim 3 discloses multiple dispensing step as such it is unclear in which does the additional dispensing of claim 5 occurs.

Each step of claim 6 recite "a sample". It is unclear if the "a sample" is directed to a different sample in each step or is the same sample subjected to respective operations of each step (also applicable to claims 11, 17-18, 24, 34-36, 38)?

As to claim 15, it is unclear how mixing comprising rotating. Is the sample located in a container?

As to claim 16, claim 14, references multiple vessels so it appears as if the "a vessel" in line 2 should be "each vessel" and "the vessel" the last line. It is unclear if the "a biological sample" the same as the "a sample".

Should the "sample" and "a sample" recited in claims 19-21 and 37 be "the sample"?

It appears the loading step of claim 36 should recite loading a vessel containing a sample into a centrifuge.

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-2, 6, 10-13, 17-25, 29-32, and 36-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464).

Petschek et al. discloses a fully automated DNA separation procedure and device therefor. The computer system contains a plurality of sub-modules and a means for communicating the commands to the device. The user can input process variables. There is a graphical user interface to display status messages. See at least

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abstract; claims; figures and descriptions thereof; column 6, lines 13-22; and column 10, lines 17-39.

Petschek et al. further teaches using a spin centrifuge with variable speed and time; pipetting to mix at variable rates and numbers of time; pipetting to dispense or withdraw fluid at variable rates and volumes. (See in particular Figure 3A.)

Petschek et al. does not disclose controlling the temperature of a function.

Lange et al. discloses an automated apparatus for isolating nucleic acids from a biological sample. The samples can be heated and cooled during various steps of the process, including lysing. See at least abstract, claims, figures, and columns 5-7 and 9-10.

It would have been obvious to those of ordinary skill in the art to add a module for temperature control to the apparatus and computer system of Petschek et al. as taught by Lange et al. in the lysis step. One would have been motivated to do so for the advantages taught by Lange. Such temperature control was routinely performed by those of ordinary skill in the art at the time of the invention. (See also Uhlen et al., U.S. Patent No. 5,330,914, at least Figure 1 and column 2, lines 53-57.)

16. Claims 6-7, 10, 24-26, 29, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464) and further in view of Johnson et al. (U.S. Patent No. 5,584,039).

Petschek et al. and Lange are applied as above. They do not require use of a dedicated processor.



Johnson et al. discloses the well-known advantages of using dedicated processors in computer systems wherein a processor is responsible for the control of multiple submodules and tasks as a means of more effectively distributing the work in a computer environment. (See Summary of the Invention.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a dedicated processor in the apparatus and computer system suggested by Petschek et al. and Lange as set forth above for the advantages taught by Johnson et al.

17. Claims 6, 8, 24-25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464) and further in view of Poulter et al. (U.S. Patent No. 6,072,795).

Petschek et al. and Lange are applied as above. They do not require use of hard code burned into the processor.

Poulter et al. discloses the use of computer systems with programs wherein said programs are burned into the processor with hard code for the advantages of reducing software programming and less software support. (See column 6, lines 8-19.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize computer systems with the programs burned into the processor with hard Code in the apparatus and computer system suggested by Petschek et al. and Lange as set forth above for the advantages taught by Poulter et al.

18. Claims 6, 9, 24-25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petschek et al. (U.S. Patent No. 5,389,339) in view of Lange (U.S. Patent No. 6,232,464) and further in view of McNutt (U.S. Patent No. 5,802,389).

Petschek et al. and Lange are applied as above. They do not require use of a programmable logic controller.

McNutt is applied as in prior Office actions and discloses the importance of providing programmable logic controllers (PLCs) which provide modular approaches. Modular systems allow for adaptation to simple and complex situations.

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a PLC with the apparatus and computer system suggested by Petschek et al. and Lange as set forth above for the advantages taught by McNutt.

***Allowable Subject Matter***

19. Claims 3-5 and 14-16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

20. Claims 34-35 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

21. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor fairly suggest each sub-module except the centrifugation sub-module is configured to control operation external to a centrifuge.

**Conclusion**

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nanthakumar; Elizabeth et al.; Dunnill; Peter et al.; Unno; Garrett; Mattheakis; Larry C. et al.; Drake, Rosemary Ann Lucy et al.; Dasseux, Jean-Louis H. et al; and Lemelson; Jerome H. disclose computer controlled devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, Telework Thurs., 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Brian R Gordon  
Primary Examiner  
Art Unit 1743

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